K072664

NOV 21 2008

Attachment B
510 (k) Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

GE Healthcare

Section a):

1. Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC division of General Electric Company
GE Medical Systems Lunar (business name)
726 Heartland Trail
Madison, WI 53717

Contact Person: James P. Raskob
Safety and Regulatory Engineering Manager
Telephone: 608-826-7425; Fax: 608-299-2132

Date Prepared: September 19th, 2007

2. Device Name: GE Lunar Femur Strength Software Option
Bone Densitometer, 21 CFR 892.1170, 90-KGI

3. Marketed Device: Advanced Hip Assessment Software Option K0011917, Hologic Hip Structural Analysis software K061561 currently in commercial distribution.

4. Device Description: The Femur Strength Software Option for GE Lunar DEXA Bone Densitometers analyzes femur BMD scans to measure hip axis length (HAL) and provides a mean reference value of HAL and HAL fracture risk indication. The software calculates hip geometry values used to estimate the structural properties of the hip such as buckling ratio, section modulus (Z), cross-sectional area (CSA) and cross-sectional moment of inertia (CSMI). The software calculates a Femur Strength Index (FSI) based on inputs of CSMI, CSA, bone mineral density (BMD), patient age, height and weight. FSI represents the biomechanical properties of the hip and provides an estimate of the risk of fracture resulting from a fall on the hip.

5. Indications for Use:

The GE Lunar Femur Strength Analysis Software option used on GE Lunar DEXA bone densitometer scans of the hip measures the hip axis length (HAL) and provides a female mean reference value of HAL. The software calculates a HAL fracture risk indicator for Caucasian females based on HAL compared to the mean reference value.

The software calculates hip geometry values used to estimate the structural properties of the hip such as sub-region lengths, angles, ratios, buckling ratio, section modulus (Z), cross-sectional area (CSA) and cross-sectional moment of inertia (CSMI). The software calculates a Femur Strength Index (FSI) based on inputs of CSMI, CSA, bone mineral density (BMD), patient age, height and weight. FSI represents the biomechanical properties of the hip and provides an estimate of the risk of fracture resulting from a fall on the hip.

The structural properties of the hip, HAL and FSI can assist the health care professional in assessment of fracture risk.

Overall fracture risk will depend on many additional factors that should be considered before making diagnostic or therapeutic recommendations. The software option does not diagnose

disease, or recommend treatment regimens, or quantify treatment effectiveness. Only the health care professional can make these judgments.

6. Comparison with Predicate Device: The Femur Strength Software Option for GE Lunar DEXA Bone Densitometers is of a comparable type and substantially equivalent to the Hologic Hip Structural Software Option and the GE Lunar Prodigy Advanced hip assessment Software option. It has the same technological characteristics, is comparable in key safety and effectiveness features, it utilizes similar design, construction, and materials, and has similar intended uses as the predicate devices.

Section b):

1. Non-clinical Tests: The device has been evaluated for electrical and mechanical safety, and has been found to conform with applicable medical device safety standards. In vitro precision and accuracy values were computed through a series of tests on phantoms and were within design specifications.
2. Clinical Tests: No clinical tests were required to establish safety or effectiveness.
3. Conclusion: Intended uses and other key features are consistent with previously cleared bone densitometer Advanced Hip Analysis Software. The design and development process of the manufacturer conforms with 21 CFR 820 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance was verified through independent evaluation with ongoing factory surveillance. The Femur Strength Software Option for GE Lunar DEXA Bone Densitometers is substantially equivalent to currently marketed devices with respect to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James P. Raskob
Safety and Regulatory Engineering Manager
GE Medical Systems Lunar
726 Heartland Trail
MADISON WI 53717

NOV 21 2008

Re: K072664
Trade/Device Name: Femur Strength Software Option for GE Lunar DEXA Bone Densitometers
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: KGI
Dated: October 21, 2008
Received: October 22, 2008

Dear Mr. Raskob:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) Indications for Use

510(k) Number (if known): K072664

Device Name: **Femur Strength Software Option for GE Lunar DEXA Bone Densitometers**

The GE Lunar Femur Strength analysis software option is an accessory to currently marketed GE Lunar DEXA bone densitometer devices, which are intended to estimate the bone mineral density and body composition (lean and fat tissue mass) of patients when medically indicated by their physicians. The Femur Strength software is intended to measure the hip axis length (HAL) and provides female adult Caucasian and Asian mean reference values of HAL from previously acquired GE Lunar femur scans.

The software calculates hip geometry values used to evaluate the structural properties of the hip, such as sub-region lengths, angles, ratios, buckling ratio, section modulus (Z), cortical thickness, cross-sectional area (CSA) and cross-sectional moment of inertia (CSMI). The software calculates a Femur Strength Index (FSI), a strength/stress ratio incorporating geometric properties of the hip such as CSMI, CSA, bone mineral density (BMD), patient age, height and weight. A ScanCheck feature is included to provide online messages to assist the operator or physician in checking that the scan was correctly taken. Color mapping of the variable density of bone images is also provided.

The values measured or computed provide additional information about the structure of the hip. They should be used in conjunction with the BMD T-score and other clinical risk factors as an aid in the diagnosis of osteoporosis and medical conditions leading to reduced bone density, and ultimately in the assessment of fracture risk.

Prescription Use XXX AND/~~OR~~ ~~Over-The-Counter Use~~ _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072664